

ECG - MI Novacode Serial Comparison

Data File: ecg_mi_nova_ct_pub File Date: 09/21/2007 Structure: Multiple rows per participant Population: CT participants

Participant ID

Variable # 1

Sas Name: ID

Sas Label: Participant ID

Type: Continuous

Usage Notes: none

Categories: Study: Administration

Baseline ECG days since randomization

Variable # 2

Sas Name: ECGBASEDAYS

Sas Label: Baseline ECG days since randomization

Type: Continuous

Usage Notes: none

Categories: Clinical Tests: ECG

Baseline ECG MI novacode

Variable # 3

Sas Name: ECGBASENOVA

Sas Label: Baseline ECG MI novacode

Type: Categorical

Values

5.0 No significant Q waves and no significant ST-T abnormalities 5.1 Q wave MI with major Q waves Q wave MI with moderate Q waves and with 5.2 ST-T abnormalities 5.3 Possible Q wave MI w/moderate Q waves w/o ST-T abnormalities Possible Q wave MI w/minor Q waves with ST-5.4 T abnormalities 5.5 Profound ST-T abnormalities without Q waves 5.6 Significant ST-T abnormalities without Q waves 5.6.1 STD or TN score >= 20 in any lead group 5.6.2 Q score < 15 in all lead groups Minor Q waves without ST-T abnormalities 5.7

Usage Notes: Use for comparison with a follow-up ECG Novacode.

Categories: Clinical Tests: ECG

Follow-up ECG days since randomization

Variable # 4

5.8

Sas Name: ECGFUDAYS

Minor ST-T abnormalities

Sas Label: Follow-up ECG days since randomization

Type: Continuous

Usage Notes: none

Categories: Clinical Tests: ECG

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Data File: ecg_mi_nova_ct_pub File Date: 09/21/2007 Structure: Multiple rows per participant Population: CT participants

Follow-up ECG visit type

Variable # 5 Usage Notes: none

Sas Name: ECGFUVTYP

Sas Label: Follow-up ECG visit type

Categorical Type:

Values

Screening 2 Semi-annual 3 Annual

Non-routine

Follow-up ECG visit year

Variable # 6 Usage Notes: none

Sas Name: ECGFUVY

Sas Label: Follow-up ECG visit year

Type: Continuous

Categories: Clinical Tests: ECG

Categories: Clinical Tests: ECG

Categories: Clinical Tests: ECG

Closest to visit (follow-up ECG)

For forms entered with the same visit type and year, indicates the one closest to that visit's target date. Valid for forms entered with an annual or semi-annual visit type.

Usage Notes: See Data Preparation Document. Variable # 7

Sas Name: ECGVCLO

Sas Label: Closest to visit (follow-up ECG)

Type: Categorical

Values

0 No Yes

Expected for visit (follow-up ECG)

The ECG was expected for this visit. ECGs were expected at screening (baseline) and at years 3, 6 and 9.

Variable # 8 Usage Notes: none

Sas Name: ECGEXP

Sas Label: Expected for visit (follow-up ECG)

Type: Categorical

Values

No Yes Categories: Clinical Tests: ECG

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Follow-up ECG MI novacode

Variable # 9

Sas Name: ECGFUNOVA

Sas Label: Follow-up ECG MI novacode

Type: Categorical

Values

5.0	No significant Q waves and no significant ST-T abnormalities
5.1	Q wave MI with major Q waves
5.2	Q wave MI with moderate Q waves and with ST-T abnormalities
5.3	Possible Q wave MI w/moderate Q waves w/o ST-T abnormalities
5.4	Possible Q wave MI w/minor Q waves with ST-T abnormalities
5.5	Profound ST-T abnormalities without Q waves
5.6	Significant ST-T abnormalities without Q waves
5.6.1	STD or TN score >= 20 in any lead group
5.6.2	Q score < 15 in all lead groups
5.7	Minor Q waves without ST-T abnormalities

Usage Notes: none

Categories: Clinical Tests: ECG

Incident novacode

Variable # 10

Sas Name: ECGINCDNTNOVA
Sas Label: Incident novacode

Minor ST-T abnormalities

Type: Categorical

Values

5.8

5.0 No significant Q waves and no significant ST-T abnormalities Q wave MI with major Q waves 5.1 5.2 Q wave MI with moderate Q waves and with ST-T abnormalities 5.3 Possible Q wave MI w/moderate Q waves w/o ST-T abnormalities 5.4 Possible Q wave MI w/minor Q waves with ST-T abnormalities 5.5 Profound ST-T abnormalities without Q waves 5.6 Significant ST-T abnormalities without Q waves 5.6.1 STD or TN score >= 20 in any lead group Q score < 15 in all lead groups 5.6.2 Minor Q waves without ST-T abnormalities 5.7 Minor ST-T abnormalities 5.8

Usage Notes: Based on serial ECG comparison. Reference: Rautaharju, P, et

al. The Novacode criteria for classification of ECG abnormalities and their clinically significant progression and regression. J

Electrocardiol. 1998 Jul;31(3):157-187.

Categories: Clinical Tests: ECG

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Categories: Clinical Tests: ECG

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Usage Notes: WHI-CCC does not count a silent MI occurring after a clinical MI.

Silent MI (evolving Q-wave; first occurrence)

First occurrence of an evolving Q-wave MI based on an incident Novacode of 5.1 or 5.2.

Sas Name: ECGSILNTMI

Variable # 11

Sas Label: Silent MI (evolving Q-wave; first occurrence)

Type: Categorical

Values

0 No 1 Yes

Possible silent MI (first occurrence)

First occurrence of a possible evolving Q-wave MI based on an incident Novacode of 5.3 or 5.4.

Variable # 12 Usage Notes: WHI-CCC does not count a silent MI occurring after a clinical MI.

Sas Name: ECGPOSMI

Sas Label: Possible silent MI (first occurrence)

Type: Categorical

Values

0 No 1 Yes

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